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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,745	08/22/2000	Anders Edlund	1103326-0633	2661

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White & Case
1155 Avenue of the Americas
New York, NY 10036-2787

EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 08/13/2002 10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/622,745

Applicant(s)

EDLUND ET AL.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 and 28-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 22-27 and 32-41 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

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DETAILED ACTION

1. Formal Matters

- A. Amendment B, filed 6/6/02, has been entered into the record.
- B. Claims 1-31 were pending in the application. Claims 1-21 and 28-31 were withdrawn as being drawn to a non-elected invention. New claims 32-41 have been added. Therefore, claims 1-41 are pending and claims 22-27 and 32-41 are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full in a previous Office Action.

2. Traversal of the Restriction Requirement

A. In Paper No. 5 dated 11/28/01, pending claims 1-31 were restricted into 5 Groups. Applicants elected Group III with traverse in Paper No. 8, filed 12/28/01. The Examiner maintained the restriction in the Office Action dated 3/12/02 and Applicants maintained their traversal in Paper No. 9, filed 6/6/02. Applicants presently argue that PCT Rules 13.1 and 13.2 are to be followed when considering unity of invention in this 371 application and that the special technical feature, the GABA_B receptor promoter, is the same in all the Groups. However, claim 1 of the first Group recites "functionally equivalent modified forms" of the GABA_B receptor promoter. The Examiner cited art by Mu et al. who teach the GABA_A receptor promoter. This is considered to be a "functionally equivalent modified form of the GABA_B receptor promoter, since they are both GABA promoters. Therefore, since art has been found on the first claimed invention, there is a lack of unity and the restriction, therefore, is deemed proper and is made FINAL. The Examiner respectfully brings to Applicants' attention that, though these claims could have been further restricted into SEQ ID NO:1 and SEQ ID NO:2 in the initial restriction requirement, it was decided that these SEQ ID NOs would be searched together.

3. Objection to the Specification

A. The objection to the specification for the omission of a drawing under 37 CFR 1.81 is maintained since, though Applicants argue that Figures 4 and 5 clearly facilitate the understanding of the invention, no Figures have been found in the application.

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4. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

A. The rejection of claims 22-27 under 35 USC 112, first paragraph, with regard to not being enabled for the integration of the promoter into the host genome has been withdrawn since numerous transient transfection techniques are known in the art. However, these claims remain rejected under 35 USC 112, first paragraph, for the reasons on pages 3-4 of the Office Action dated 3/12/02 and new claims 32-41 are also rejected. Claim 22 recites “functionally equivalent modified forms” and “active fragments.” Applicants argue that Examples 2-4 and Figures 2 and 3 of the specification give a detailed enabling description and actual examples of the construction of the promoter-reporter gene constructs and their uses in screening. However, Example 4 does not recite any specific SEQ ID NO of any promoters. It only discloses that promoters can be truncated or altered to identify important regions as determined by transfection experiments. Examples 5 and 6 show that various regions of the promoters of SEQ ID NO:1 and 2, and functionally equivalent modified forms of these promoters have been identified, but no other GABA promoters have been identified and studied in this application. Therefore, the scope of claim 22 with regard to methods of screening compounds using *any and all* GABA_B receptor promoters, or any functionally equivalent modified form, or active fragment thereof, from promoters which have not been identified, is excessive, given that Applicants have only identified two GABA_B receptor promoters (SEQ ID NO:1 and 2). Furthermore, since no Figures are present in the application, the Examiner cannot use this information as argued by the Applicants in further determining if the scope of the claimed invention is enabled.

Furthermore, claims 22, 32 and 37 recite the use of GABA promoters which hybridize to SEQ ID NO:1 or 2 under stringent conditions. Though these conditions are defined in claims 32 and 37, and are stringent, the breadth of the claims is still excessive. These promoters are close to 4000 bases. Therefore, even under the most stringent conditions, hundreds of DNA molecules may hybridize to these promoters. Applicants have only identified 2 promoters, SEQ ID NO:1 and 2. Therefore, the breadth of the claims regarding any promoters which hybridize to SEQ ID NO:1 or 2 is excessive. Applicants can overcome this part of the rejection by amending the claims to recite hybridization along with, for example, that the molecules which hybridize are at least 95% identical to SEQ ID NO:1 or 2. Claims 23-27, 33-36 and 38-41 are rejected since they depend from rejected claims.

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4. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 22-27 remain rejected under 35 USC 112, first paragraph, for the reasons on pages 4-5 of the Office Action dated 3/12/02. Claim 22 recites “functionally equivalent modified forms” and “active fragments.” Applicants argue that Example 5 and Figures 4 and 5 of the specification give numerous examples of the construction of the promoter-reporter gene constructs and their uses in screening. However, Example 5 only shows that various regions of the promoters of SEQ ID NO:1 and 2, and functionally equivalent modified forms thereof, have been identified and studied, but no other GABA promoters have been identified and studied in this application. Therefore, the specification only provides written description of methods using SEQ ID NO:1 and 2 and functionally modified forms thereof and not for methods of screening compounds using *any and all* GABA_B receptor promoters, or any functionally equivalent modified form, or active fragment thereof, from promoters which have not been identified. Furthermore, since no Figures are present in the application, the Examiner cannot use this information as argued by the Applicants in further determining if the claimed invention is adequately described.

Furthermore, regarding “stringent hybridization conditions,” this part of the rejection is being maintained since, in claim 23, Applicants do not specifically recite the exact conditions in the claim. Applicants argue that page 6, lines 16-20 of the specification recites exact conditions. However, these conditions are given by example only (“defined by e.g. hybridization to...”). Claims 24-27 are rejected since they depend from rejected base claims.

5. Claim Rejections - 35 USC § 112, second paragraph

A. Claim 23 remain rejected under 35 USC 112, second paragraph, for the reasons already of record on page 5 of the Office Action dated 3/12/02. Applicants argue that page 6, lines 16-20 of the specification recites exact conditions and that there is no indefiniteness. However, these conditions are given by example only (“defined by e.g. hybridization to...”). Claims 24-27 are rejected since they depend from rejected base claims.

6. Conclusion

A. No claim is allowable.

Gary L. Kunz
GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1000

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
August 12, 2002